



DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. PTO-P-2020-0032]

RIN 0651-AD48

Electronic Submission of a Sequence Listing, a Large Table, or a Computer Program

Listing Appendix in Patent Applications

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Final rule; correction.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) makes corrections to a final rule published on October 14, 2021, that amended the rules of practice to permit higher-capacity physical media to be submitted to the USPTO. This rule fixes typographical errors.

DATES: This rule is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Mary C. Till, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, at Mary.Till@uspto.gov; or Ali Salimi, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patents, at Ali.Salimi@uspto.gov.

SUPPLEMENTARY INFORMATION:

On October 14, 2021, the USPTO published a final rule amending the rules of practice to permit higher-capacity physical media to be submitted to the USPTO (86 FR 57035). That final rule, which went into effect on November 15, 2021, contained two incorrect cross-references in 37 CFR 1.77 to the methods by which a sequence listing may be submitted to the USPTO. This final rule corrects those cross-references to avoid any confusion.

Section 1.77(b)(13) is revised to reference § 1.821(c)(2) for a “Sequence Listing” that is submitted as a Portable Document Format (PDF) file via the USPTO patent electronic filing system and § 1.821(c)(3) for a “Sequence Listing” that is submitted on physical sheets of paper. The references published in the October 14, 2021, final rule—§ 1.821(c)(1)(ii) and § 1.821(c)(1)(iii)—do not exist.

Rulemaking Considerations

A. Administrative Procedure Act

This rulemaking corrects typographical errors in a rulemaking permitting higher-capacity physical media to be submitted to the USPTO. The changes in this rulemaking involve a rule of agency practice and procedure and/or an interpretive rule. *See Perez v. Mortg. Bankers Ass’n*, 135 S. Ct. 1199, 1204 (2015) (Interpretive rules “advise the public of the agency’s construction of the statutes and rules which it administers.” (citation and internal quotation marks omitted)); *Nat’l Org. of Veterans’ Advocates v. Sec’y of Veterans Affairs*, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (rule that clarifies interpretation of a statute is interpretive); *Bachow Commc’ns Inc. v. FCC*, 237 F.3d 683, 690 (D.C. Cir. 2001) (Rules governing an application process are procedural under the Administrative Procedure Act.); *Inova Alexandria Hosp. v. Shalala*, 244 F.3d 342, 350 (4th Cir. 2001) (Rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims.).

Accordingly, prior notice and opportunity for public comment for the changes in this rulemaking are not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. *See Perez*, 135 S. Ct. at 1206 (Notice and comment procedures are required neither when an agency “issue[s] an initial interpretive rule” nor “when it amends or repeals that interpretive rule.”); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336-37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice and comment rulemaking for “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice” (quoting 5 U.S.C. 553(b)(A))).

In addition, the Director of the USPTO finds good cause under 5 U.S.C. 553(b)(B) to waive the notice and comment requirements of the Administrative Procedure Act. As discussed above, the changes in this rulemaking involve correcting typographical errors in two cross-references in the final rule published on October 14, 2021. These changes are administrative in nature and will have no substantive impact on the evaluation of a patent application. If this rule were delayed to allow for notice and comment, this would lead to confusion as to the sections intended to be cross-referenced.

The Director of the USPTO also finds good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effectiveness. As discussed above, the changes in this rulemaking involve correcting typographical errors in two cross-references in the final rule published on October 14, 2021. These changes are administrative in nature and will have no substantive impact on the evaluation of a patent application. The purpose of a delay in effectiveness is to allow affected parties time to modify their behaviors, businesses, or practices to come into compliance with new regulations. This rule imposes no additional requirements on the affected entities. Therefore, the requirement for a 30-day delay in effectiveness is not applicable, and the rule is made effective immediately upon publication.

B. Regulatory Flexibility Act

As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 or any other law, neither a Regulatory Flexibility Act analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) is required. *See* 5 U.S.C. 603.

C. Executive Order 12866 (Regulatory Planning and Review)

This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

D. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the USPTO consider the impact of paperwork and other information collection burdens imposed on the

public. The USPTO has determined that there are no new requirements for information collection associated with this final rule.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Biologics, Courts, Freedom of information, Inventions and patents, Reporting and recordkeeping requirements, Small businesses.

For the reasons stated in the preamble and under the authority contained in 35 U.S.C. 2, as amended, the USPTO amends 37 CFR part 1 as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), unless otherwise noted.

2. Amend § 1.77 by revising paragraph (b)(13) to read as follows:

§ 1.77 Arrangement of application elements.

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(b) * * *

(13) “Sequence Listing,” required by § 1.821(c), that is submitted as a Portable Document Format (PDF) file (as set forth in § 1.821(c)(2)) via the USPTO patent electronic filing system or on physical sheets of paper (as set forth in § 1.821(c)(3)).

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Andrew Hirshfeld,
Commissioner for Patents,
Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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